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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/596,370	06/19/2000	James M. White	1721-1	3966

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HARRISON & EGBERT  
412 MAIN STREET  
7TH FLOOR  
HOUSTON, TX 77002

EXAMINER
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CHORBAJI, MONZER R

ART UNIT	PAPER NUMBER
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1744

DATE MAILED: 05/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/596,370	WHITE, JAMES M.	
	<b>Examiner</b>	<b>Art Unit</b>	
	MONZER R CHORBAJI	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 March 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 21-35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21-35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 June 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

**This final office action is in response to the amendment received on 03/01/2004**

#### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 21, 27, 29, and 33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In claim 21, line 8; applicant recites the feature "in valveless fluid communication". The specification and the drawings teach the use of valves (62 and 54) between the disinfectant line (unlabeled portion of the disinfectant line prior to valve 62) and the biological line (unlabeled portion of the biological line prior to valve 54). The specification on pages 6, 9, and 11 teaches of placing valves on the biological fluid line and the disinfectant line. The same reasoning applies to claims 27, 29, and 33.

#### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 21-25, 29-31, and 33-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson (U.S.P.N. 5,087,420) in view of Aubrey et al (U.S.P.N. 3,857,409) and further in view of Kern, Jr. et al (U.S.P.N. 6,000,418).

With respect to claims 21, 29, and 33, Jackson discloses a method and a device for disposal of biological fluids (col.1, lines 57-60) such that the device includes a housing (11), a water flow inlet (20) and an outlet (22), a biological fluid line (col.3, lines 33-36) such that the water fluid line and the biological fluid line are mixed together (20, 24, and 26). Jackson further teaches a disinfectant line (32) in communication with the water flow line (water inside 26) such that the disinfectant line has an inlet outwardly of the housing (23). Further the disinfectant line (32 and water within 26) and the biological fluid line (24 and water within 26)) are connected with the water flow line. Jackson device further includes a disinfectant line (32) connected in valveless fluid communication (no valves are present on both the biological fluid line and the disinfectant line) with biological fluid line (24) between the water flow line (30) and an inlet of the biological fluid line (38) wherein the biological fluid line being substantially blood (col.1, lines 59-60). Furthermore, the disinfectant line (32) is in fluid

communication with the water flow line (water inside 26). Jackson goes on to disclose a method of disposing biological fluids (col.4, lines 51-68 and columns 5-6) that the following steps: connecting the biological fluid line in valveless relation to a disinfectant line (24 is connected to 32 through 26), connecting a water flow line to an outlet of the biological fluid line and the disinfectant line (30 is connected to the outlets of 38 and 32), mixing the biological fluid and the disinfectant together (mixed in 26), and discharging the water and the mixed biological fluid and disinfectant from water flow line (22).

However, Jackson fails to teach that solely the flow of water causes the suction and mixing of both the disinfectant and the biological fluid lines (venturi means) and the housing contains no pumps. Aubrey et al housing includes no pumps (col. 7, lines 64-67 and col.8, lines 1-6), but there is no teaching that solely the flow of water causes the suction and mixing of both the disinfectant and the biological fluid lines. Kern, Jr. et al discloses the concept that the flow of water causes the suction and mixing of different fluids (col.5, lines 17-23). As a result, it would have been obvious to one having ordinary skill in the art to modify the method and device of Jackson to include the concept of a venturi means since such means provides for stability of the mixing ratio as well as finite incremental control of the chemical mixture due to the fact that the chemical injection is proportional to the water pressure flow (Kern, Jr. et al, col.5, lines 48-51).

With respect to claim 22, Jackson device has water flow inlet (20) means and outlet means (22) such that the inlet means is for passing water and the outlet means for releasing a mixture of the biological fluid and the water and the disinfectant (col.6, lines 41-45).

With respect to claim 23, Jackson device includes a water inlet (20) communicating with one end of water flow line (30a) and an outlet means (22) connected to water flow line (46) on an opposite end of water flow line such that outlet means for passing a flow of liquid to a sewer (col.6, lines 46-47).

With respect to claim 24, Jackson device includes a pipe (39) communicating with the water flow line (30) such that both communicate with each other through 26), the disinfectant line (32) connected to the pipe (through 26) a distance from the water flow line (30) and between an inlet of the pipe (unlabeled inlet for 39) and water flow line (30) such that the biological fluid (38) mixing with the disinfectant (32) in pipe (39).

With respect to claim 25, Jackson device includes a valve means (40) connected to the pipe (39) such that if for example the valve (40) is opened then the rate of the biological fluid is reduced since all the biological fluid is emptied from (26) to reservoir (27).

With respect to claim 31, Jackson treated fluid is interconnected to a sewer (22 and col.6, lines 45-47).

With respect to claim 34, Jackson method includes connecting the disinfectant line (32) to the biological fluid line (38 through 26) between an inlet of the biological fluid line (36) and the outlet of the disinfectant line (outlet of 32).

With respect to claim 30, Kern, Jr. et al discloses the concept of venturi means such that solely a water flow across openings of various different fluids creates a suction force (col.5, lines 17-23).

6. Claims 26-28, 32, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson (U.S.P.N. 5,087,420) in view of Aubrey et al (U.S.P.N. 3,857,409) and further in view of Kern, Jr. et al (U.S.P.N. 6,000,418) and Griffiths (U.S.P.N. 5,914,047).

With respect to claims 26-28, 32, and 35, Jackson, Aubrey et al, and Kern, Jr. et al all fails to disclose containers for biological and disinfectant fluids such that the fluid lines are inserted into the containers, however; Griffiths discloses the following: a suction line for insertion into a biological fluid container (70A), a biological fluid container (46A) having a top level (68), inserting an inlet of the biological fluid line into a container of biological fluid (clo.7, lines 33-35), a disinfectant container (80) having a top level (82), and a suction line for insertion into a disinfectant fluid container (84). Thus, it would have been obvious to one having ordinary skill in the art to modify the method and the device of Jackson to include a biological fluid container since it functions as a container for untreated liquid waste (Griffiths, col.7, lines 31-32).

#### ***Response to Arguments***

7. Applicant's arguments filed on 03/01/2004 have been fully considered but they are not persuasive.

On page 11 of the response, applicant argues, "The prior art Aubrey system is a very complicated mixing apparatus employing a variety of pumps and valves". The examiner disagrees. The Aubrey system can optionally not employ any pump as explained in col.8, lines 4-6. The system in the instant application does employ valves

as indicated in figures 1-2, 42, 62, and 54 and in the specification on pages 6, 9, and 11.

On page 11 of the response, applicant argues, "The Jackson patent is quite distinguishable from the present invention in that the Jackson patent is a timed batch process". The claims do not recite a continuous system. In addition, the Jackson reference is connected to an outside water fluid line (col.4, lines 55-56) as in the instant application. Also, the instant system is a batch system since it treats a filled biological fluid container one at a time and not continuously. See figure 1, 50.

On page 12 of the response, applicant argues, "The Griffiths patent describes a static mixing apparatus 76 for the purpose of mixing the biological fluid with the disinfectant". The only reason for using the Griffiths reference is for the limitations of having a biological and disinfectant fluid containers and not for how the Griffiths device functions.

The Kern, Jr. et al reference is used for the single reason to show that it is known in the art of mixing that the sole flow of water creates suction that draws other fluids in and results in mixing (venturi means). See col.5, lines 17-28 in the Kern, Jr. et al reference.

### ***Conclusion***

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).



9. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MONZER R CHORBAJI whose telephone number is (571) 272-1271. The examiner can normally be reached on M-F 8:30-5:00.

11. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ROBERT J WARDEN can be reached on (571) 272-1281. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

12. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Art Unit: 1744

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Monzer R. Chorbaji *MRC*  
Patent Examiner  
AU 1744  
05/17/2004

*Jill Warden*  
Jill Warden  
Supervisory Patent Examiner  
Technology Center 1700